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10/551,884

02/06/2007

Patrick Joseph Caroline

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11/01/2007

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EXAMINER

GREECE, JAMES R

ART UNIT

PAPER NUMBER

2873

MAIL DATE

DELIVERY MODE

11/01/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/551,884

Applicant(s)

CAROLINE ET AL.

Examiner

James R. Greece

Art Unit

2873

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/30/2005.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

*Detailed Action*

Applicant cooperation is requested in correcting any errors of which applicant may become aware in the specification.

*Status of the Application*

Claims 1-14 are pending in this application

If the applicant is aware of any prior art or any other co-pending application not already of record, he/she is reminded of his/her duty under 37 CFR 1.56 to disclose the same.

*Drawings*

There are no objections to the applicant's drawings at this time.

*Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 5-7, and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Stoyan (USPAT 6,010,219).

In regard to claim 1, Stoyan teaches as claimed:

A soft contact lens having a generally concave posterior surface for fitting to the eye of a wearer, (see figure 2) and a convex anterior surface, (see figure 2) the contact lens having mechanical properties and/or a geometric shape such that when the lens is fitted to the eye the pressure applied to the eye by or via the lens will vary in a radial direction between at least one zone of higher pressure and at least one zone of lower pressure, the pressure gradient between said zones, and the location of said zones, being selected so as to cause a dimensional change to the surface layer of the cornea of the eye to thereby at least temporarily cause the refractive state of the eye to change (See col 1, 35-55)

In regard to claim 2, Stoyan teaches as claimed:

Wherein said posterior surface has a shape that differs from the contour of the eye such that a first annular portion of the lens at a selected radial distance from the center of the lens will be closer to the surface of the eye than a second annular portion of the lens at a different second selected radial distance from the center of the lens (See figure 2)

In regard to claim 3, Stoyan teaches as claimed:

Wherein the pressures applied to the eye at the first annular portion and at the second annular portion are such as to define a pressure gradient which is sufficiently steep that epithelial thickness will tend to increase from the zone of high pressure towards the zone of low pressure (See col. 1, lines 35-55)

In regard to claim 5, Stoyan teaches as claimed:

Wherein the lens is formed of a material with oxygen transmissibility greater than 87 barrers (see col.4, lines 61-67 & col. 5, lines 1-18)

In regard to claim 6, Stoyan teaches as claimed:

Wherein the lens has an elastic modulus of between 0.2 and 10.0 MPa (see col.4, lines 61-67 & col. 5, lines 1-18)

In regard to claim 7, Stoyan teaches as claimed:

Wherein the lens is comprised of a silicone hydrogel material (see col.4, lines 61-67 & col. 5, lines 1-18)

In regard to claim 9, Stoyan teaches as claimed:

Wherein the lens has a center thickness of between 0.04 mm and 0.31 mm (See col. 3, lines 17-20)

In regard to claim 10, Stoyan teaches as claimed:

Having an annular zone of lower pressure at a distance less than approximately 4 mm from the center of the lens (See col. 5, lines 53-54)

In regard to claim 11, Stoyan teaches as claimed:

Having an annular zone of higher pressure at a distance of approximately between 3 mm and 6 mm from the center of the lens (See figure 2 & col. 5, lines 52-55)

3. Claims 12-14 are rejected under 35 U.S.C. 102(a, e) as being anticipated by Mitsui (USPUB 2003/0095232).

In regard to claim 12, Mitsui teaches:

determining the required refractive correction for the eye; (see paragraph 0088-0089) characterizing the surface shape of at least that part of the eye which is to be subjected to reshaping; (See paragraph 0087) and selecting a soft lens formed of a material and having a

geometric configuration such that when fitted to the eye will apply pressures to the surface of the eye in such manner as to assist in the required corneal reshaping (See paragraph 0091).

In regard to claim 13, Mitsui teaches:

Wherein said selection process involves a modeling process adapted to predict anticipated pressures and different zones of the wearer's eye (See paragraph 0076)

In regard to claim 14, Mitsui teaches:

Said modeling process is a finite element modeling process (0091-0092)

#### *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stoyan (USPAT 6,010,219) as applied to claim 1 above, and further in view of Volk (USPAT 3,482,906).

In regard to claim 8, Stoyan does not explicitly disclose the following as claimed:

Wherein the lens has a back vertex power of between +10D and -35D

However Volk teaches this limitation. (Volk teaches between +20 and -20 which includes the applicant's range)

It would have been obvious for one having ordinary skill in the art of contact lens design to design a lens having a specific back vertex power as taught by Volk for the predictable result of providing necessary vision correction.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The applicant does not explicitly claim or define what is meant by the term stable. Possible interpretations include stable in shape when everted and placed upon the eye, stable when everted but not in contact with the eye. The applicant not specifically claiming this limitation has left the claim open to multiple and conflicting interpretations. However the examiner has interpreted the claim to mean everted and stable when placed upon the eye and implying the lens is functional in everted and non everted states.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James R. Greece whose telephone number is 571-272-3711. The examiner can normally be reached on M-Th 7:30-6.

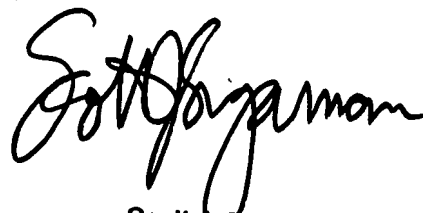
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ricky Mack can be reached on 571-272-2333. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James R. Greece  
Patent Examiner  
571-272-3711



Scott J. Sugarman  
Primary Examiner